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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

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**BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Application Number: 10/523,657
Filing Date: February 04, 2005
Appellant(s): CARLINO, STEFANO

Clifford W. Browning
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed November 7, 2009 appealing from the Office action mailed July 6, 2009.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relied Upon**

| | | |
|---|---|---|
| 5,503,848 | PERBELLINI et al | 4-1996 |
| 6,489,467 | CARLINO et al | 12-2002 |
| WO 00/44925 | CARLINO et al | 8-2000 |

**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 4-9 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 6,489,467 in view of Perbellini et al (U.S. Patent No. 5,503,848). The claims of the US Patent No. 6,489,467 are directed to a process for purifying high molecular weight hyaluronic acid, passing hyaluronic acid formulation through a filter having a pore size of less than 0.45 um (claim 1), such as 0.2 um (claim 19). However, said claims do not include a step of concentrating said formulation by applying a vacuum and boiling off water until a specified concentration is achieved. Perbellini et al disclose a process for preparing hyaluronic acid for injectable preparation which comprises dissolving hyaluronic acid in water in an apparatus equipped with a heating system and vacuum system until the desired concentration is achieved and placing hyaluronic acid formulation into sterile

containers. Thus, it would have been prima facie obvious to a person having ordinary skill in the art at the time of the claimed invention to concentrate the formulation of hyaluronic cid prepared by the process claimed in the U.S. Patent No. 6,489,467 under vacuum and boiling of water until the desired concentration is achieved as disclosed by Perbellini et al because said person would have expected to achieve a pharmaceutical formulation ready for pharmaceutical use.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 4-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carlino et al (WO 00/44925 or U.S. Patent No. 6,6489,467) in view of Perbellini et al (U.S. Patent No. 5,503,848).

Carlino et al disclose a process for preparing a purified hyaluronic acid formulation comprising sterilizing hyaluronic acid by passing an aqueous formulation through a filter having a pore size of 0.2 um (page 10 of the WO Patent) but do no disclose the step of concentrating said formulation under vacuum until a desired concentration is achieved. However, since Perbellini et al disclose preparation of a hyaluronic acid formulation wherein said formulation is subjected to a vacuum until a desired concentration is achieved and parceling said formulation into a sterile containers (column 10, lines 21-37), it would have been prima facie obvious to a person having ordinary skill in the art at the time of the claimed invention to concentrate hyaluronic acid formulation disclosed by Carlino et al and concentration said formulation under vacuum as disclosed by Perbellini et al in order to achieve a formulation which is suitable to the parceled out into sterile containers.

(10) Response to Argument

With respect to the obviousness-type double patenting rejection, Appellant contends that the present invention is not simply the use of evaporation under vacuum to concentrate a solution of hyaluronic acid but lies in the provision for preparing a ready-to-use aqueous pharmaceutical formulation of hyaluronic acid at a specified concentration. Appellant further contends that in the process claimed in the U.S. patent No. 6,489,467, the obtained solution is freeze dried to obtain a dry powder of purified hyaluronic acid. These arguments have not been found persuasive. Claims 1-8 and 11-28 do not include a freeze drying step. Further, Perbellini et al disclose in column 10, lines 21-37 parceling out filtered solution of hyaluronic acid into sterile containers.

Appellant argues that Perbellini et al do not disclose or suggest the step of concentrating hyaluronic acid to a desired concentration by vacuum concentration methods. However, it is the examiner's position the disclosure by Perbellini et al of dissolving hyaluronic acid in water in a suitable apparatus, equipped with a heating system and vacuum so as to achieve a concentration ranging between 1 mg/ml and 40 mg/ml reads on the claimed step of concentrating an aqueous formulation by applying a vacuum until a desired concentration is achieved.

With respect to the rejection of claims 1 and 4-9 under 35 USC 103 as being obvious over Carlino et al in view of Perbellini et al, Appellant contends that Carlino et al disclose that the filter sterilized hyaluronic acid may be freeze-dried to obtain a dry powder of hyaluronic acid in a purified form which can be used to prepare pharmaceutical compositions and does not teach concentrating a filter-sterilized solution of hyaluronic acid by applying vacuum and boiling of water. Appellant further contends that Perbellini et al do not disclose any step of concentrating a solution of hyaluronic acid by a vacuum concentration method but simply disclose dissolving hyaluronic acid in water up to the desired concentration. These arguments have not been found persuasive. It is noted that Carlino et al disclose freeze-drying hyaluronic acid. However note that the present claims contain the term "comprising", are therefore open-ended and encompass any other additional step. Further, it is the examiner's position that the teaching by Perbellini et al in column 10 of dissolving hyaluronic acid in an apparatus equipped with a heating system and a vacuum reads on the claimed step of concentrating aqueous formulation of hyaluronic acid under vacuum. Further note that

that Perbellini et al further disclose in column 10 parceling the filtered solution into suitable sterile containers. Note the terminology "ready for pharmaceutical use" (claim 1) reads on the immediate use. It would have been obvious to a person having ordinary skill in the art at the time of the claimed invention to immediately use the purified hyaluronic acid and only freeze-drying hyaluronic acid for long storage use. Therefore, the claimed process is still deemed prima facie obvious over the cited prior art.

**(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Elli Peselev

/Elli Peselev/

Primary Examiner, Art Unit 1623

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